



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/782,594

02/12/2001

John R. Bianchi

RTI- 112R

9490

52727

7590

11/16/2009

REGENERATION TECHNOLOGIES, INC.

c/o MCANDREWS, HELD & MALLOY

500 WEST MADISON STREET

34TH FLOOR

CHICAGO, IL 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

11/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN R. BIANCHI, C. RANDAL MILLS,
P. J. GORHAM, MICHAEL ESCH, KEVIN C. CARTER,
PAT COLEMAN, KEVIN ROSS, HARRY W. RAMBO,
DARREN G. JONES and DAYNA BUSKIRK

Appeal 2009-006360
Application 09/782,594
Technology Center 3700

Decided: November 16, 2009

Before: WILLIAM F. PATE III, JENNIFER D. BAHR and
LINDA E. HORNER, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 26-30. App. Br 6. We have jurisdiction under 35 U.S.C. § 6(b). This Appeal is related to Appeal number 2009-000600 in Application number 10/387,322 and Appeal number 2009-014427 in Application number 09/905,683.

The claims are directed to an assembled bone graft for implantation into a human patient. Claim 26, reproduced below, is illustrative of the claimed subject matter:

26. An assembled bone graft, said assembled bone graft assembled outside the body and suitable for implantation into a human patient, said assembled bone graft comprising: a plurality of machined allograft bone portions layered to form a graft unit, and pins comprising cortical bone traversing said graft unit for holding said graft unit together as an assembled bone graft, wherein said assembled bone graft does not include an adhesive.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Coates	US 5,989,289	Nov. 23, 1999
Siebels ¹	EP 0 517 030 A2	Dec. 9, 1992

Claims 26-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Siebels and Coates.

¹ References to Siebels are to the English translation entered into the record February 27, 2006.

ISSUE

Appellants argue claims 26-30 as a group. App. Br. 13-25. We select claim 26 as the representative claim, and claims 27-30 stand or fall with claim 26. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner found that Siebels discloses the structure of claim 1 except that Siebels fails to disclose making the implant pieces of cortical bone. Ans. 3-4. The Examiner found that Coates teaches that it was known to make similar spinal implants of cortical bone. *Id.* at 3-4. The Examiner concluded that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone because of its superior properties in vivo, as taught by Coates. *Id.* at 4.

The Appellants contend that the Examiner improperly relied upon conclusory statements without a rational underpinning in order to reach a conclusion of obviousness. App. Br. 14-15. Appellants further contend that the Examiner failed to properly consider the references as a whole, specifically, by ignoring portions of Siebels and Coates that would lead away from the claimed invention. App. Br. 15-22. Appellants further contend that there would not have been a reasonable expectation of success in combining the teachings of Siebels and Coates in the manner proposed by the Examiner. App. Br. 22-24. Lastly, Appellants contend that the proposed combination would not have taught all the claimed elements because neither reference specifically teaches making a pin comprising cortical bone. App. Br. 24-25.

In light of these contentions, we must determine whether Appellants have established that the Examiner erred in concluding that the subject

matter of claim 26 would have been obvious to one having ordinary skill in the art.

FINDINGS OF FACT

1. As required by claim 26, Siebels discloses an assembled implant 10 manufactured outside a body into which it is to be implanted (e.g., between vertebral bodies 50, 51). P. 4, ll. 18-25; p. 7, l. 23 - p. 8, l. 8.
2. Siebels' implant comprises a plurality of portions (e.g., disks 11-14) layered to form a unit 10. P. 8, ll. 11-21.
3. Siebels' implant additionally comprises anchoring pins 17 traversing the unit 10 for holding the unit 10 together. P. 9, ll. 7-18.
4. Siebels discloses that bone cement and/or adhesive may be used in place of, or supplementary to, the anchoring means, i.e., pins 17. P. 6, ll. 6-7; p. 11, ll. 16-22; p. 12, ll. 9-10.
5. Siebels fails to disclose that the disks 11-14 or pins 17 are made from cortical bone.
6. Siebels discloses that the disks 11-14 are preferably made from carbon-fiber reinforced plastic and the pins 17 may be constructed of the same or another material. P. 6, ll. 10-13. Siebels suggests that the disks can be manufactured from any biologically compatible material. P. 10, ll. 14-15.
7. Siebels does not criticize or discourage the use of cortical bone to construct the implants.
8. Coates recognizes the disadvantages of constructing an implant from a foreign body, such as stress shielding, subsidence, and permanence. Col. 2, ll. 34-48.

9. Coates also recognizes that while it would be preferable to construct an implant from bone graft in order to promote osteogenesis and to avoid the disadvantages of implants made from foreign bodies, constructing an implant from a bone graft, such as a bicortical Cloward dowel, has typically yielded an implant with poor mechanical properties, such as low compressive strength. Col. 2, l. 49 - col. 3, l. 9.
10. Coates teaches that because cortical bone exhibits high compressive strength as compared to other bone graft materials, it is a preferred material for use in constructing intravertebral implants 110. Coates recognizes that an allograft may be a suitable source for cortical bone. Coates, col. 2, ll. 61-62; col. 11, ll. 42-46.
11. Coates suggests making implants any suitable size or shape and recognizes that cortical bone may be shaped to the desired configuration by conventional machining methods adapted to bone in a known manner. Coates, col. 11, ll. 52-64.

PRINCIPLES OF LAW

The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. The key to supporting any prima facie conclusion of obviousness under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418.

The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR*, 550 U.S. at 416. A prima facie conclusion of obviousness may be supported by a showing that the claims are directed to a process, machine, manufacture, or composition of matter already known in the prior art that is altered by the mere substitution of one element for another known in the field, and such modification yields a predictable result. *See id.* (citing *United States v. Adams*, 383 U.S. 39, 40 (1966)). The Court further stated that “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417. When considering obviousness of a combination of known elements, the operative question is thus “whether the improvement is more than the predictable use of prior-art elements according to their established functions.” *Id.*

Whether a reference teaches away from a claimed invention is a question of fact. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, ... would be led in a direction divergent from the path that was taken by the applicant.” *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (quoting *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)). “When a piece of prior art ‘suggests that the line of development flowing from the reference’s disclosure is unlikely to be

productive of the result sought by the applicant’ the piece of prior art is said to ‘teach away’ from the claimed invention.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983). However, “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

ANALYSIS

Siebels discloses the basic structure of the implant of claim 26. Facts 1-4. Siebels, however, fails to disclose that its disks are made from allograft bone, and its pins from cortical bone, to thereby form a graft unit, as required by claim 26. Fact 5. Coates demonstrates that it was known in the art at the time of Appellants’ invention to use cortical bone to construct intravertebral implants. Facts 10, 11. Modifying the Siebels implant such that the disks and pins are made from cortical bone, is the result of applying the known technique taught by Coates, to a known device, ready for improvement, in order to yield the predictable result of providing a high strength implant without the disadvantages associated with fabricating the implant from a foreign body. *See* Fact 8. As such, this modification would have been obvious to one having ordinary skill in the art. Furthermore, modifying the Siebels implant to substitute one biologically compatible

material, carbon-fiber reinforced plastic, with another, cortical bone, amounts to the simple substitution of one known element for another. *See* Facts 6, 9 and 10. Substitution of materials is expressly suggested by Siebels (*See* Fact 6) and the substitution of cortical bone for the carbon-fiber reinforced plastic would have been obvious to one having ordinary skill in the art.

Appellants argue that the Examiner relies upon only conclusory statements which are insufficient to establish a rationale underpinning to support the conclusion of obviousness. App. Br. 14-15. To support this allegation, Appellants point out that the Examiner points to Coates in lieu of explicitly articulating reasons for making the proposed modification. The fact that the Examiner points to the references in lieu of explicitly articulating reasons for modifying a reference does not, however, without more, establish that the Examiner has not provided proper support for a rejection under 35 U.S.C. § 103. In this instance, the references themselves articulate both a reason (*see* Fact 8) and a suggestion (*see* Fact 6) to make the proposed modification. There is no basis to conclude that the Examiner improperly relied upon hindsight to reach a conclusion of obviousness as Appellants suggest.

Appellants further argue that because Siebels prefers manufacturing the implants from carbon-fiber reinforced plastic and recognizes that it is “easy” to do so, Siebels teaches away from fabricating the implant from cortical bone because cortical bone cannot be manufactured by those techniques Siebels would consider “easy.” App. Br. 15-20. Appellants assert, therefore, that the suggestion of Siebels to use any biologically compatible material is actually limited to those materials which are easy to

manufacture. Appellants note that Coates states that it has been extremely difficult or impossible to manufacture implants from cortical bone, and conventional machining methods must be adapted to bone in order to do so. App. Br. 20-22. This argument is not persuasive. Merely disclosing a particular material, such as carbon-fiber reinforced plastic, as preferable would not lead one of ordinary skill in the art away from the use of an alternate material such as cortical bone, when reading the reference as a whole—especially when the reference specifically suggests that alternate materials may be employed. See Fact 6. The fact that a particular material exhibits desirable characteristics, such as ease of manufacturing, also would not lead one of ordinary skill in the art away from the use of alternate materials because one of ordinary skill in the art would recognize that alternate materials may also exhibit similar desirable characteristics. Appellants improperly interpret the teachings of Coates by concluding that Coates teaches that cortical bone is not a material that could be easily manufactured. The quoted portion of Coates on page 21 of Appellants’ Brief describes the perceived difficulty in constructing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either. This statement does not support Appellants’ conclusion that Coates teaches it is extremely difficult or impossible to develop an implant from cortical bone. Firstly, the quoted portion of Coates is not discussing use of cortical bone, and secondly, the quoted portion of Coates is taken from the background discussion. The entirety of the reference evidences the state of the art, not only the background discussion. See *e.g.*, *In re Lamberti*, 545 F.2d 747, 750, (CCPA 1976)(“The use of patents as references is not limited to what the patentees

describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.”). As Appellants acknowledge, Coates does teach that conventional machining methods must be adapted to bone in order to fabricate the implant from cortical bone, but this does not suggest that the known manufacturing method described in Coates must be further modified to machine bone as Appellants assert. Rather, it suggests that Coates knew of conventional machines that have already been modified for this purpose. *See* Fact 11. Thus, one of ordinary skill in the art would not draw the conclusion from Coates that implants made from cortical bone would be particularly difficult to manufacture simply because they are made by techniques different from Siebels as Appellants suggest. For these reasons, Siebels does not criticize or discourage the use of cortical bone as taught by Coates to construct the implants and therefore does not teach away from the claimed invention wherein cortical bone is used to construct the implants. Fact 7.

Appellants argue that no basis for a reasonable expectation of success has been established for combining Siebels and Coates. App. Br. 22-24. Appellants assert that because of the difficulties with making bone grafts as described in Coates, there would not have been a reasonable expectation of success that the implants could be assembled from multiple pieces. App. Br. 24. As noted above, however, one of ordinary skill in the art would not draw the conclusion from Coates that implants made from cortical bone would be particularly difficult to manufacture. Appellants further assert that Coates is directed to a single piece implant as opposed to multiple pieces, and while each of Siebels and Coates provide an implant of sufficient strength, neither reference provides a basis for concluding that the proposed combination

would successfully provide this property. App. Br. 23-24. Again, the test for obviousness is not whether the claimed invention is expressly suggested in any one or all of the references. The fact that Coates does not specifically teach the use of cortical bone applied to an implant having multiple pieces pinned together does not establish that one of ordinary skill in the art would not have had a reasonable expectation of success in applying the cortical bone material taught by Coates to the implant disclosed in Siebels. Absolute predictability that the substitution will be successful is not required. All that is required is a reasonable expectation of success. *See In re O'Farrell* 853 F.2d 894, 903- 904 (Fed. Cir. 1988). Coates describes using known machining techniques to manufacture a structure from cortical bone which, from a machining standpoint, is more complex than the pins and disks described by Siebels due to its noncircular profile and asymmetry. This would have provided one of ordinary skill in the art with a reasonable expectation that the pins and disks of Siebels could also be manufactured from cortical bone. Furthermore, Coates' description of the desirable structural characteristics of cortical bone would have provided one of ordinary skill in the art with a reasonable expectation that the pins and disks described by Siebels would possess the necessary strength if instead fabricated from cortical bone.

Appellants argue that Coates does not describe pins made from cortical bone. App. Br. 24-25. The test for obviousness, however, is not whether the claimed invention is expressly suggested in any one or all of the references. Nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed.

Cir. 1986). Siebels is cited to demonstrate an implant made by assembling multiple pieces and pins. It is not required that those pieces and pins must also be present in Coates in order to sustain a rejection under 35 U.S.C. § 103(a). The combined teachings of Siebels and Coates would have suggested that the components of the Siebels implant, namely the disks and pins, could be constructed from the non-foreign, high-strength cortical bone taught by Coates. An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418.

CONCLUSION OF LAW

On the record before us, Appellants have not established that the Examiner erred in concluding that the subject matter of claim 26 would have been obvious to one having ordinary skill in the art.

DECISION

For the above reasons, the Examiner’s rejection of claims 26-30 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

Vsh

Appeal 2009-006360
Application 09/782,594

REGENERATION TECHNOLOGIES, INC.
c/o MCANDREWS, HELD & MALLOY
500 WEST MADISON STREET
34TH FLOOR
CHICAGO IL 60661